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CONNOLLY BOVE LODGE & HUTZ LLP
1875 EYE STREET, N.W.
SUITE 1100
WASHINGTON, DC 20006

EXAMINER	
WEST, JEFFREY R	

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2857	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,027	DEN HEUVEL ET AL.	
	Examiner	Art Unit	
	Jeffrey R. West	2857	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *139,140,144-150,153,155-162,164-171 and 173-180* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *139,140,144-150,153,155-162,164-171 and 173-180* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 June 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 13, 2009, has been entered.

Claim Objections

3. Claims 139, 156, and 165 are objected to because of the following informalities:

In claim 139, line 11, “so as to to perform” should be ---so as to perform---.

In claim 156, line 10, "or customized one the clinician" should be ---or customized on the clinician---.

In claim 165, line 14, “tests, , wherein” should be ---tests, wherein---.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 174-176 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 174 is considered to be vague and indefinite because of the sentence fragment, “means for performing, on said cochlear implant, said one or more after-care tests on the and” and because it specifies that the tests are performed both “independent of the clinician subsystem” and “substantially independent of the clinician subsystem”.

Claims 175 and 176 are rejected under 35 U.S.C. 112, second paragraph, because they incorporate the lack of clarity present in parent claim 174.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 139, 140, 144, 147-150, 155, 156, 159-162, 164, 165, 168-171, 173, 174, and 178, as may best be understood, are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,916,291 to Givens et al.

With respect to claim 139, Givens discloses a system for performing after-care of a recipient of a cochlear implant (column 10, lines 49-58 and column 13, lines 47-53) comprising: a clinician subsystem having a clinician interface (column 8, lines 63-66, column 9, lines 12-24, and column 16, lines 20-29) configured to receive one or more clinician inputs that at least one of select or customize cochlear implant after-care tests (column 9, lines 35-43, column 15, line 59 to column 16, line 29) and a recipient subsystem (column 8, lines 57-63, column 10, lines 17-24, and column 15, lines 29-58) configured to receive the one or more selected or customized after-care tests from the clinician subsystem (column 20, lines 15-17 and column 23, lines 41-44 and 54-60) and wherein the recipient subsystem communicates with the cochlear implant so as to perform the one or more after-care tests selected or customized on the clinician subsystem substantially independent of the clinician subsystem to generate result data indicative of the result of the after-care tests(column 19, lines 48-60, column 20, lines 24-46 and column 23, lines 29-44 and 54-63) for subsequent use by said clinician subsystem (column 13, lines 58-63), wherein said clinician

subsystem is further configured to receive said result data from said recipient subsystem (column 9, lines 47-51).

With respect to claim 140, Givens discloses further comprising: a device interface configured to communicatively couple said recipient subsystem and the cochlear implant (column 10, lines 49-58, column 19, lines 34-59 and Figure 11).

With respect to claim 144, Givens discloses wherein said clinician subsystem and said recipient subsystem are physically remote with respect to one another and communicate via the Internet (column 8, line 57 to column 9, line 11).

With respect to claim 147, Givens discloses further comprising: a storage medium configured to store said one or more after-care tests (column 14, lines 57-59).

With respect to claim 148, Givens discloses further comprising: a storage medium configured to store said result data (column 9, lines 24-33).

With respect to claim 149, Givens discloses wherein said storage medium is a portable storage medium (column 8, lines 3-6).

With respect to claim 150, Givens discloses wherein the recipient subsystem is further configured to deliver the result data to the clinician subsystem, and further wherein the clinician subsystem is further configured to perform an assessment of the result data (column 18, lines 63-66).

With respect to claim 155, Givens discloses wherein said clinician subsystem is configured to initiate the one or more after-care tests performed by the recipient subsystem (column 20, lines 17-23 and column 20, line 66 to column 21, line 8).

With respect to claim 156, Givens discloses a method for performing after-care of a recipient of a cochlear implant comprising (column 10, lines 49-58 and column 13, lines 47-53): receiving one or more inputs at a clinician interface (column 8, lines 63-66, column 9, lines 12-24, and column 16, lines 20-29) that at least one of select or customize one or more cochlear implant after-care tests (column 9, lines 35-43 and column 15, line 59 to column 16, line 29), delivering said one or more after-care tests to a recipient subsystem (column 9, lines 35-43), performing, on the cochlear implant, said one or more after-care tests selected or customized on the clinician subsystem to generate result data indicative of the result of the after-care test (column 9, lines 47-51 and column 13, lines 58-63), wherein the after-care tests are performed by the recipient subsystem substantially independent of the clinician subsystem (column 19, lines 48-60, column 20, lines 24-46 and column 23, lines 29-44 and 54-63), and delivering the result data to the clinician subsystem (column 9, lines 47-51 and column 13, lines 58-63).

With respect to claim 159, Givens discloses wherein the recipient subsystem further comprises a storage medium, and wherein the method further comprises storing said one or more after-care tests (column 14, lines 57-59).

With respect to claim 160, Givens discloses further comprising storing said result data in a storage medium of the recipient subsystem (column 9, lines 24-33 and column 23, lines 23-27).

With respect to claim 161, Givens discloses wherein the storage medium is a portable storage medium (column 8, lines 3-6).

With respect to claim 162, Givens discloses wherein said delivering said one or more after-care tests to the recipient subsystem comprises delivering said one or more after-care tests via the Internet (column 8, line 57 to column 9, line 11).

With respect to claim 164, Givens discloses wherein said performing said one or more after-care tests further comprises initializing the one or more tests being performed by the recipient subsystem with inputs received from the clinician interface (column 20, lines 17-23 and column 20, line 66 to column 21, line 8).

With respect to claim 165, Givens discloses a computer readable medium comprising computer code instructions which, when executed by a computer system (column 8, lines 7-22), implement a method of performing after-care of a recipient of a cochlear implant (column 10, lines 49-58 and column 13, lines 47-53), the method comprising: receiving one or more inputs at a clinician interface that at least one of select or customize one or more cochlear implant after-care tests (column 8, lines 63-66, column 9, lines 12-24, column 15, line 59 to column 16, line 29), delivering said one or more after-care tests to a recipient subsystem (column 9, lines 35-43), comprising a recipient interface (column 8, lines 57-63, column 10, lines 17-24, and column 15, lines 29-58); performing, on the cochlear implant, said one or more after-care tests selected or customized on the clinician subsystem to generate result data indicative of the result of the after-care tests (column 9, lines 47-51 and column 13, lines 58-63), wherein the after-care tests are performed by the recipient subsystem substantially independent of the clinician subsystem (column 19, lines 48-60, column

20, lines 24-46 and column 23, lines 29-44 and 54-63) and delivering the result data to the clinician subsystem (column 9, lines 47-51 and column 13, lines 58-63)

With respect to claim 168, Givens discloses wherein the recipient subsystem further comprises a storage medium, and wherein the method further comprises storing said one or more after-care tests in the recipient subsystem (column 14, lines 57-59).

With respect to claim 169, Givens discloses wherein the recipient subsystem further comprises a storage medium, and wherein the method further comprises storing said result data in said recipient subsystem (column 9, lines 24-33 and column 23, lines 23-27).

With respect to claim 170, Givens discloses wherein the storage medium is a portable storage medium (column 8, lines 3-6).

With respect to claim 171, Givens discloses wherein said delivering said one or more after-care tests to the recipient subsystem comprises delivering said one or more after-care tests via the Internet (column 8, line 57 to column 9, line 11).

With respect to claim 173, Givens discloses wherein said performing said one ore more after-care tests further comprises initializing the one or more tests being performed by the recipient subsystem with inputs received from the clinician interface (column 20, lines 17-23 and column 20, line 66 to column 21, line 8).

With respect to claim 174, Givens discloses a system for performing after-care of a recipient of a cochlear implant (column 10, lines 49-58 and column 13, lines 47-53) comprising: means for receiving one or more inputs via a clinician subsystem

(column 8, lines 63-66, column 9, lines 12-24, and column 16, lines 20-29) that at least one of select or customize one or more cochlear implant after-care tests (column 9, lines 35-43, column 15, line 59 to column 16, line 29); means for delivering said one or more after-care tests to a recipient subsystem (column 9, lines 35-43); means for performing, on said cochlear implant, said one or more after-care tests on the and independent of the clinician subsystem (column 19, lines 48-60, column 20, lines 24-46 and column 23, lines 29-44 and 54-63), to generate result data indicative of the result of the after-care tests (column 9, lines 47-51 and column 13, lines 58-63), wherein the after-care tests are performed by the recipient subsystem substantially independent of the clinician subsystem (column 19, lines 48-60, column 20, lines 24-46 and column 23, lines 29-44 and 54-63), and means for delivering the result data to the clinician subsystem (column 9, lines 47-51 and column 13, lines 58-63).

With respect to claim 178, Givens discloses wherein at least one of the one or more after-care tests comprises a comparison of a measured neural response threshold to a previously measured neural response threshold (column 4, lines 3-10 and column 22, lines 11-35).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 145, 146, 153, 157, 158, 166, 167, 175-177, 179, and 180, as may best be understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Givens in view of U.S. Patent No. 5,626,629 to Faltys et al.

As noted above, the invention of Givens teaches many of the features of the claimed invention, and while the invention of Givens does teach testing, using customized tests, a cochlear implant which generates test results, Givens is not explicit in storing such tests/results in the cochlear implant. Further, while Givens does teach coupling the prosthesis to a recipient subsystem, Givens is not explicit in specifying that the coupling is via a cable. Further still, while Givens teaches performing a plurality of after-care tests, including a comparison of a measured neural response threshold to a previously measured neural response threshold, Given is not explicit in specifying that at least one of the one or more after-care tests comprises a cochlear implant integrity check, determines whether the dynamic range of each of a plurality of electrodes is set correctly, and/or evaluates the effectiveness of the cochlear implant.

Faltys discloses a system for performing one or more tests (column 7, lines 10-13 and 22-26, column 8, lines 44-55, column 9, lines 6-16, and column 10, lines 10-12) on a cochlear implant having one or more implantable components implanted in a recipient (column 5, lines 19-21) comprising: a clinician subsystem, comprising a clinician interface (column 5, lines 35-50), configured to enable a clinician to provide

one or more clinician input from said clinician interface to perform one or more of selecting and customizing the one or more tests for the recipient (column 6, lines 51-55, column 7, lines 41-65, column 10, lines 26-53, and column 15, lines 34-55, and column 22, lines 51-53); and a recipient subsystem, comprising a recipient interface (column 5, lines 51-66), configured to receive one or more recipient input, from said recipient interface (column 4, lines 22-25), and to generate the result data (column 6, lines 51-55, column 14, line 53 to column 15, line 6), wherein said clinician subsystem is further configured to received said result data from said recipient subsystem (column 8, lines 10-43) wherein the cochlear implant is configured to store said selected or customized one or more tests (column 6, lines 51-55 and column 9, lines 40-61), store said result data (column 9, lines 57-61), and is coupled to said recipient subsystem using a cable (column 5, line 51 to column 6, line 17 and Figure 1). Faltys further teaches wherein at least one of the one or more after-care tests comprises a cochlear implant integrity check (column 16, lines 19-35), a comparison of a measured neural response threshold to a previously measured neural response threshold (column 7, lines 1-49 and column 8, lines 55-60), determines whether the dynamic range of each of a plurality of electrodes is set correctly (column 4, lines 2-4, column 9, lines 21-49, and column 10, lines 17-25), and/or evaluates the effectiveness of the cochlear implant (column 18, lines 15-22).

It would have been obvious to one having ordinary skill in the art to modify the invention of Givens to explicitly store the tests/results in the cochlear implant, as taught by Faltys, because, as suggested by Faltys, the combination would have

improved the system of Givens by storing important information in the cochlear implant itself so that the data will be readily available for future use and/or to provide to a clinician when the network connection fails or during routine in-office clinician visits (column 2, lines 51-65, column 6, lines 51-55 and column 9, lines 40-61).

It would have been obvious to one having ordinary skill in the art to modify the invention of Givens to explicitly specify that the coupling is via a cable, as taught by Faltys, because one having ordinary skill in the art would recognize a cable as a conventional means for connecting a cochlear implant to an interface and, as suggested by Faltys, the combination would have provides a suitable, accurate, and secure means for connecting the prosthesis and interface for communication in Givens (column 5, line 51 to column 6, line 17 and Figure 1).

It would have been obvious to one having ordinary skill in the art to modify the invention of Givens to explicitly specify that at least one of the one or more after-care tests comprises a cochlear implant integrity check, determines whether the dynamic range of each of a plurality of electrodes is set correctly, and/or evaluates the effectiveness of the cochlear implant, as taught by Faltys, because, as suggested by Faltys, the combination would have improved the overall operation of Givens by ensuring that the cochlear implant is subject to a wider variety of tests for a wider variety of conditions, thereby ensuring that the electrodes are in the correct sequence (column 16, lines 19-35), the electrodes are operating in a proper range (column 4, lines 2-4, column 9, lines 21-49, and column 10, lines 17-25), and that the device provides the best sounding operation (column 18, lines 15-22).

10. Claims 139, 140, 144-150, 153, 155-162, 164-171 and 173-180, as may best be understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,626,629 to Faltys et al. in view of U.S. Patent No. 5,909,497 to Alexandrescu.

With respect to claim 139, Faltys discloses a system for after-care (column 7, lines 10-13 and 22-26, column 8, lines 44-55, column 9, lines 6-16, and column 10, lines 10-12) of a recipient of a cochlear implant (column 5, lines 19-21) comprising: a clinician subsystem having a clinician interface (column 5, lines 35-50), configured to receive one or more clinician inputs that at least one of select or customize one or more cochlear implant after-care tests (column 6, lines 51-55, column 7, lines 41-65, column 10, lines 26-53, and column 15, lines 34-55, and column 22, lines 51-53); and a recipient subsystem (column 5, lines 51-66) configured to receive the one or more selected or customized after-care tests from the clinician subsystem, and wherein the recipient subsystem communicates with the cochlear implant to as to perform the one or more after-care tests selected or customized on the clinician subsystem (column 4, lines 22-25) to generate result data indicative of the result of the after-care tests for subsequent use by said clinician subsystem (column 6, lines 51-55, column 14, line 53 to column 15, line 6), wherein said clinician subsystem is further configured to receive said result data from said recipient subsystem (column 8, lines 10-43).

With respect to claim 140, Faltys discloses a device interface configured to communicatively couple said recipient subsystem and the cochlear implant (column 5, line 51 to column 6, line 17 and Figure 1).

With respect to claim 145, Faltys discloses that the cochlear implant is configured to store said one or more after-care tests (column 6, lines 51-55 and column 9, lines 40-61).

With respect to claim 146, Faltys discloses that the cochlear implant is configured to store said result data (column 9, lines 57-61).

With respect to claim 147, Faltys inherently discloses a storage medium configured to store said one or more after-care tests (column 6, lines 43-55).

With respect to claim 148, Faltys inherently discloses a storage medium configured to store said result data (column 6, lines 60-63 and column 7, lines 41-65).

With respect to claim 149, Faltys discloses that said storage medium is a portable storage medium (column 22, lines 35-44).

With respect to claim 150, Faltys discloses that the recipient subsystem is further configured to deliver the result data to the clinician subsystem, and further wherein the clinician subsystem is further configured to perform an assessment of the result data (column 8, lines 2-43).

With respect to claim 153, Faltys discloses a cable coupled between said device interface and said cochlear implant (column 5, line 51 to column 6, line 17 and Figure 1)

With respect to claim 155, Faltys discloses that said clinician subsystem is configured to initiate the one or more after-care tests performed by the recipient subsystem (column 15, lines 19-28, column 15, lines 37-48, column 16, lines 36-38).

With respect to claim 156, Faltys discloses a method for performing after-care (column 7, lines 10-13 and 22-26, column 8, lines 44-55, column 9, lines 6-16, and column 10, lines 10-12) of a recipient of a cochlear implant (column 5, lines 19-21) comprising: receiving one or more inputs at a clinician interface (column 5, lines 35-50) that at least one of select or customize one or more cochlear implant after-care tests (column 6, lines 51-55, column 7, lines 41-65, column 10, lines 26-53, and column 15, lines 34-55, and column 22, lines 51-53); delivering said one or more after-care tests to a recipient subsystem (column 5, lines 51-66, column 6, lines 51-55 and column 9, lines 40-61), performing, on the cochlear implant, said one or more after-care tests selected or customized on the clinician subsystem to generate result data indicative of the result of the after-care test (column 6, lines 51-55, column 14, line 53 to column 15, line 6); and delivering the result data to the clinician subsystem (column 8, lines 2-43).

With respect to claim 157, Faltys discloses further comprising storing said one or more after-care tests in the cochlear implant (column 6, lines 51-55 and column 9, lines 40-61).

With respect to claim 158, Faltys discloses further comprising storing said result data in the cochlear implant (column 9, lines 57-61).

With respect to claim 159, Faltys inherently discloses that the recipient subsystem further comprises a storage medium and wherein the method further comprises storing said one or more after-care tests (column 6, lines 51-55 and column 9, lines 40-61).

With respect to claim 160, Faltys inherently discloses further comprising storing said result data in a storage medium of the recipient subsystem (column 9, lines 57-61).

With respect to claim 161, Faltys discloses that the storage medium is a portable storage medium (i.e. as part of a portable device) (column 6, lines 51-55 and column 9, lines 40-61).

With respect to claim 164, Faltys discloses that performing said one or more after-care tests further comprises initializing the one or more tests being performed by the recipient subsystem with inputs received from the clinician interface (column 16, lines 36-49).

With respect to claim 165, Faltys discloses a computer readable medium comprising computer code instructions which, when executed by a computer system (column 5, lines 19-25) implement a method of performing after-care of a recipient of a cochlear implant (column 5, lines 19-21), the method comprising: receiving one or more inputs (column 7, lines 10-13 and 22-26, column 8, lines 44-55, column 9, lines 6-16, and column 10, lines 10-12) at a clinician interface (column 5, lines 35-50) that at least one of select or customize one or more cochlear implant after-care tests (column 6, lines 51-55, column 7, lines 41-65, column 10, lines 26-53, and column

15, lines 34-55, and column 22, lines 51-53); delivering said one or more after-care tests to a recipient subsystem (column 6, lines 51-55 and column 9, lines 40-61), comprising a recipient interface (column 5, lines 51-66); performing, on the cochlear implant, said one or more after-care tests selected or customized on the clinician subsystem to generate result data indicative of the result of the after-care tests (column 6, lines 51-55, column 14, line 53 to column 15, line 6); and delivering the result data to the clinician subsystem (column 8, lines 2-43).

With respect to claim 166, Faltys discloses that the method further comprises storing said one or more after-care tests in the cochlear implant (column 6, lines 51-55 and column 9, lines 40-61).

With respect to claim 167, Faltys discloses that the method further comprises storing said result data in the cochlear implant (column 9, lines 57-61).

With respect to claim 168, Faltys inherently discloses that the recipient subsystem further comprises a storage medium and wherein the method further comprises storing said one or more after-care tests in the recipient subsystem (column 6, lines 51-55 and column 9, lines 40-61).

With respect to claim 169, Faltys inherently discloses that the recipient subsystem further comprises a storage medium and wherein the method further comprises storing said result data in said recipient subsystem (column 9, lines 57-61).

With respect to claim 170, Faltys discloses that the storage medium is a portable storage medium (i.e. as part of a portable device) (column 6, lines 51-55 and column 9, lines 40-61).

With respect to claim 173, Faltys discloses that performing said one or more after-care tests further comprises: initializing the one or more tests being performed by the recipient subsystem with inputs received from the clinician interface (column 16, lines 36-49).

With respect to claim 174, Faltys discloses a system for performing after-care of a recipient of a cochlear implant (column 5, lines 19-21) comprising: means for receiving one or more inputs (column 7, lines 10-13 and 22-26, column 8, lines 44-55, column 9, lines 6-16, and column 10, lines 10-12) via a clinician subsystem (column 5, lines 35-50) that at least one of select or customize one or more cochlear implant after-care tests (column 6, lines 51-55, column 7, lines 41-65, column 10, lines 26-53, and column 15, lines 34-55, and column 22, lines 51-53); means for delivering said one or more after-care tests (column 6, lines 51-55 and column 9, lines 40-61) to a recipient subsystem (column 5, lines 51-66); means for performing, on said cochlear implant, said one or more after-care tests to generate result data indicative of the result of the after-care tests (column 6, lines 51-55, column 14, line 53 to column 15, line 6); and means for delivering the result data to the clinician subsystem (column 8, lines 2-43).

With respect to claim 175, Faltys discloses that the cochlear implant comprises means for storing said one or more after-care tests (column 6, lines 51-55 and column 9, lines 40-61).

With respect to claim 176, Faltys discloses that the cochlear implant comprises means for storing said result data (column 9, lines 57-61).

With respect to claim 177, Faltys discloses wherein at least one of the one or more after-care tests comprises a cochlear implant integrity check (column 16, lines 19-35).

With respect to claim 178, Faltys discloses wherein at least one of the one or more after-care tests comprises a comparison of a measured neural response threshold to a previously measured neural response threshold (column 7, lines 1-49 and column 8, lines 55-60).

With respect to claim 179, Faltys discloses wherein the cochlear implant comprises a plurality of electrodes (column 6, lines 24-26), and wherein at least one of the one or more after-care tests determines whether the dynamic range of each of the plurality of electrodes is set correctly (column 4, lines 2-4, column 9, lines 21-49, and column 10, lines 17-25).

With respect to claim 180, Faltys discloses wherein at least one of the one or more after-care tests evaluates the effectiveness of the cochlear implant (column 18, lines 15-22).

As noted above, the invention of Faltys teaches many of the features of the claimed invention and while the invention of Faltys does teach a computer that

process software instructions and output signals to perform testing of a cochlear implant through a recipient interface as well as allowing visualization of results by a clinician through a clinician interface, Faltys does not explicitly indicate that the interfaces are provided by separate remote computers connected by the Internet to allow independent testing to be performed by the recipient interface.

Alexandrescu teaches a programmable hearing aid instrument and programming method thereof including a recipient interface (column 4, lines 4-19) provided by a computer located remote from a clinician interface (column 8, lines 19-33) wherein the recipient interface is operable to obtain software instructions from the hearing prosthesis (column 5, lines 37-49), perform independent testing using the recipient interface (column 8, lines 19-33) and deliver data specific to the hearing prosthesis (i.e. results) electronically to the clinician/specialist interface (column 5, lines 17-20) using the Internet (column 7, line 66 to column 8, line 4).

It would have been obvious to one having ordinary skill in the art to modify the invention of Faltys to explicitly indicate that the interfaces are provided by separate remote computers connected by the Internet to allow independent testing to be performed by the recipient interface, as taught by Alexandrescu, because, as suggested by Alexandrescu, the combination would have improved the recipient's programming of the device by providing specific programming for the environment in which the recipient is intending to use the device (column 8, lines 19-33) while allowing an experienced specialist to obtain response data from the environment to

aid in tailoring the response parameters for the particular environment (column 1, lines 11-18, column 5, lines 17-20, and column 8, lines 5-18).

Response to Arguments

11. Applicant's arguments with respect to claims 139,140,144-150,153,155-162,164-171 and 173-180 have been considered but are moot in view of the new ground(s) of rejection.

The following arguments, however, are noted:

With respect to the teachings of Givens with respect to independent claim 139, Applicant argues:

> As noted above, Givens is exclusively directed to a system for evaluating a patient's hearing loss, and merely provides tones to the patient. Not only is the testing of Givens not equivalent to "after-care of a recipient of a cochlear implant," but the system of Givens also completely fails to disclose any type of system that is configured to receive inputs "that at least one of select or customize one or more after-care tests" as recited, in part, in claim 139. It would be appreciated that the adjustment of tones is not equivalent to the selection or customization of "one or more [cochlear implant] after-care tests."
>
> Furthermore, Givens fails to disclose "[t]he identical invention.., in as complete detail as is contained" in claim 139 because Givens fails to disclose any system which is configured to "receive the one or more after-care tests, and.., perform the one or more after-care tests selected or customized on the clinician subsystem." (See, Givens, col. 2, Ins. 18- 56.) As noted, the system of Givens merely includes a patient terminal which provides tones to the patient. Givens lacks any disclosure indicating that the terminal is capable of performing cochlear implant "after-care tests" as recited, in part, in claim 139.
>
> Therefore, because Givens does not disclose the system of claim 139 in "as complete detail as contained in the claim," Applicants assert that Givens fails to anticipate the invention of claim 139. As such, Applicants respectfully request that the rejection of claim 139 under 35 U.S.C. § 102(e) be reconsidered, and that it be withdrawn.

The Examiner first asserts that while Applicant argues that "Not only is the testing of Givens not equivalent to 'after-care of a recipient of a cochlear implant,' but the system of Givens also completely fails to disclose any type of system that is configured to receive inputs 'that at least one of select or customize one or more after-care tests'" as "It would be appreciated that the adjustment of tones is not equivalent to the selection or customization of 'one or more [cochlear implant] after-care tests'", Applicant has not clearly indicated why the tests of Givens cannot be considered to be after-care tests.

Turning to the specification, Applicant indicates that after-care can include "continual or regular monitoring of the operation of the device", "comparison of current performance against historical records for that device", "continual checking of the stability of the technical and physiological operation of the device", "updating the device", "technical service of the external parts of the system", "distribution of spare parts and replacement batteries", "ongoing recipient counseling", "standard checks of the recipient's threshold and comfort levels and the integrity of the overall system including speech processor and microphone" (see page 3, lines 13-21).

The Examiner also asserts that newly added claim 178, specifies that "wherein at least one of the one or more after-care tests comprises a comparison of a measured neural response threshold to a previously measured neural response threshold" which is taught by Givens, specifically:

> Alternatively, or in addition thereto, a biotelemetry mode may be used, wherein a local device measures middle ear pressure, compliance characteristics, changes and/or distortion product emission levels. These biotelemetry measures can be obtained with tympanometry as well as the

> measurement of otoacoustic emissions associated with cochlear hair cell responses in the ear (such as distortion product emission, transient and/or spontaneous). (column 4, lines 3-10)
>
> FIG. 15 is a graph of distortion product (DP) amplitude (dB SPL) over a stimulus frequency range of interest (shown as f.sub.2 frequency over about a 500-10,000 Hz). This type of format can be described as a "Dpgram". During the evaluation, the number of stimulus frequencies per octave and the number of octaves in the test may be manipulated by the expert site. In the example shown, a diagnostic evaluation using DPOAE's for four frequencies per octave over a range of about 500-10,000 Hz). The enclosed region in the graph corresponds to a "normal" range for DPOAE amplitudes in a desired population (such as infant, pediatric, adolescents, adult, or senior populations). The points (shown as shaded circles) drawn proximate the enclosed region corresponds to the DPOAE amplitude of the patient being tested. The DPgram can include a line corresponding to an upper limit for noise within the ear canal of a corresponding population segment (in substantially the same testing environment). As shown, the upper limit is set at the 95th percentile of an adult population). The results shown in this figure are deemed normal. For more information on otoacoustic tests, see James W. Hall, Handbook of Otoacoustic Emissions, (Singular Publishing 2000); Frederick N. Martin, Introduction to Audiology, A study Guide, (Prentice-Hall, 1991), the contents of which are hereby incorporated by reference as if recited in full herein. (column 22, lines 11-35).

Applicant then provides similar arguments with respect to claims 156, 165, and 174 and the combination of Givens in view of Faltys which are not considered to be persuasive for the reasons provided above. The Examiner also asserts that with respect to the teachings of Faltys, Applicant argues:

> As noted above, Faltys is exclusively directed to a system for initially fitting a cochlear implant to a patient and is used by a clinician to set a patient's threshold and comfort levels, dynamic range, and programming a gain level. (See, Faltys, col. 1, Ins. 6-17; col. 6, Ins. 32- col. 8, In. 23.) Not only is the testing of Faltys not equivalent to "after-care of a recipient of a cochlear implant," but the system of Faltys also completely fails to disclose any type of system that is configured to receive inputs "that at least one of select or customize one or more after-care tests" as recited, in part, in claim 139.
>
> Furthermore, Faltys fails to disclose any system which receives "the one or more selected or customized after-care tests from the clinician subsystem, and

> wherein the recipient subsystem communicates with the cochlear implant so as to perform the one or more after-care tests selected or customized on the clinician subsystem." (See, Faltys, col. 6, Ins. 32- col. 8, In. 23.) As noted, the system of Faltys requires a clinician to operate the tests, evaluate objective feedback and adjust stimulation signals applied to the patient. (See, Faltys, col. 6, Ins. 32- col. 8, In. 23.) Faltys lacks any disclosure indicating that the system of Faltys is capable of providing a performing cochlear implant "after-care tests" as recited, in part, in claim 139.

The Examiner again asserts that while Applicant argues that “Not only is the testing of Faltys not equivalent to ‘after-care of a recipient of a cochlear implant,’ but the system of Faltys also completely fails to disclose any type of system that is configured to receive inputs ‘that at least one of select or customize one or more after-care tests’”, Applicant has not clearly indicated why the tests of Faltys cannot be considered to be after-care tests.

The Examiner also asserts that newly added claims 177-180, specify that “at least one of the one or more after-care tests comprises a cochlear implant integrity check”, “at least one of the one or more after-care tests comprises a comparison of a measured neural response threshold to a previously measured neural response threshold”, “wherein at least one of the one or more after-care tests determines whether the dynamic range of each of the plurality of electrodes is set correctly”, and “wherein at least one of the one or more after-care tests evaluates the effectiveness of the cochlear implant”, respectively, which is taught by Faltys, specifically:

With respect to claim 177, Faltys discloses wherein at least one of the one or more after-care tests comprises a cochlear implant integrity check:

After the audiologist and patient have revised or established threshold and maximum comfortable stimulation levels for each of the channels of the implantable cochlear stimulator 46, the sequence of the electrodes is checked using a sweep function (Block 1034, FIG. 3A). An exemplary sweep screen is shown in FIG. 5F. Solid round dots represent the stimulation level to be applied during the sweep, which for the illustrated case are shown at the maximum comfortable stimulation levels. As with the editing screen discussed above, the stimulate "button" is located in the lower left corner of the sweep screen, and the "up" and "down" arrows used to adjust the stimulation levels are shown in the lower right corner of the sweep screen. "Left" and "right" arrows located near the bottom center of the sweep screen allow the audiologist to adjust the sweep direction, i.e., from the first electrode in the electrode array to the last, or vice versa.(column 16, lines 19-35)

With respect to claim 178, Faltys discloses wherein at least one of the one or more after-care tests comprises a comparison of a measured neural response threshold to a previously measured neural response threshold:

Another important aspect of the programmer unit 14 is the ability to record objective measurements taken from the patient either interoperatively or postoperatively. For example, one common objective measurement of value in the fitting of the implantable cochlear stimulator 46 is a stapedius reflex measure. Stapedius reflex is measured interoperatively by gradually increasing stimulation current applied through at least one channel of the electrode array 50 (FIG. 1) until contraction of the stapedius reflex muscle is observed in response to stimulation from the implantable cochlear stimulator 46 (or implant). Postoperatively, stapedius reflex is measured using a readily available audiological testing apparatus known as an audiological impedance bridge 51. In order to determine stapedius reflex postoperatively, the audiological impedance bridge is set to reflex decay mode to observe changes in middle ear compliance due to stimulations measured with probe 52 in the ipsi-on contralateral ear. As with the interoperative measurement of stapedius reflex, stimulation current is gradually increased until muscle contraction (through middle ear compliance) is detected by the audiological impedance bridge in response to stimulation from the implant 46.

Another objective measurement useful in the fitting of the patient system is the EABR. The EABR refers to the electrically elicited auditory brainstem response detected in response to stimulation through the electrode array 50 by the implant 46. The EABR is measured through electrodes 54 placed on the

patient's earlobes and on top of the patient's head using an audiological EABR instrument 53, such as is known in the art. In order to measure the EABR, stimulation delivered through the electrode array 50 is gradually increased until an objective threshold of stimulation is observed through the audiological EABR instrument, which measures scalp potentials correlated with stimulation levels in the time domain. The audiological EABR instrument is preferably coupled to the programmer unit 14 through a serial interface in order to facilitate time domain correlations between the stimulation delivered and the scalp potentials measured. Stimulation and measurments generally must be repeated 50-100 times to separate the desired signal from noise. The programmer unit 14 advantageously supports such a protocol. (column 7, lines 1-49)

Typically, the audiologist will ask the patient to compare the stimulation on adjacent channels, and then will make an adjustment to one of the channels until the channels balance in stimulation. Then, the audiologist will ask the patient to subjectively evaluate the stimulation provided by each of a next pair of channels. One of the channels in the next pair of channels is typically one of the two channels initially compared, and the other is a channel that has not yet been evaluated. The audiologist continues asking the patient to compare the stimulations on pairs of channels until each of the channels of the patient system 12 has been compared with each of its adjacent channels. (column 8, lines 55-60)

With respect to claim 179, Faltys discloses wherein the cochlear implant comprises a plurality of electrodes, and wherein at least one of the one or more after-care tests determines whether the dynamic range of each of the plurality of electrodes is set correctly:

In one variation, the method includes mapping an estimated input dynamic range to an adjusted threshold stimulation current; and mapping a zero decibel gain to an adjusted comfortable stimulation current, the input dynamic range being measured relative to the zero decibel gain. (column 4, lines 2-4)

The maximum comfortable stimulation levels for each of the channels are mapped to a 0 dB point on the audio spectrum analyzer, and the threshold stimulation levels are mapped to some lower point dependent upon the input dynamic range selected. The input dynamic range selected determines the range of sound amplitudes that will result in stimulation currents being generated at levels between the threshold stimulation level and the maximum comfortable stimulation level on the electrode array. By increasing the input dynamic range,

> i.e., moving the input dynamic range toward 0 dB, the level of background sounds "heard" by the patient is decreased because the level of sound needed before stimulation current at the threshold stimulation level is applied is greater. Similarly, by decreasing the input dynamic range, i.e., moving the input dynamic range down, away from the 0 dB point, the level of background heard by the patient is increased because the level of sound needed before the threshold stimulation level is applied is less. (column 9, lines 21-39)
>
> As mentioned above, filter band assignments for each of the channels can be adjusted by the programmer unit 14. Such adjustment of the filter bands not only allows the audiologist to customize the frequency ranges (or bands) that will cause stimulation current to be applied to each of the electrodes, respectfully, but allows the audiologist to reorder the electrodes tonically so as to compensate for conditions such as foldover of the electrode array, which can occur during implantation. (column 10, lines 17-25)

With respect to claim 180, Faltys discloses wherein at least one of the one or more after-care tests evaluates the effectiveness of the cochlear implant:

> In addition to, or instead of, the audiologist using the on-screen graphic equalizer to adjust channel gains, the patient may use the first eight slider-type equalizer potentiometers 30 of the graphic equalizer board 28 (FIG. 1) to adjust the channel gains. In this way, the patient is able to directly determine and adjust the channel gains to produce the most desirable, i.e., best "sounding", stimulations to the patient. (column 18, lines 15-22)

With respect to the combination of Faltys in view of Alexandrescu with respect to independent claim 139, Applicant argues:

> As noted above, Alexandrescu is exclusively directed to a system for providing programs to an acoustic hearing aid. (See, Alexandrescu, col. 3, ln. 59-col. 4, ln. 19.) Not only is the testing of Alexandrescu not equivalent to "after-care of a recipient of a cochlear implant," but the system of Alexandrescu also completely fails to disclose any type of system that is configured to receive inputs "that at least one of select or customize one or more after-care tests" as recited, in part, in claim 139.
>
> Furthermore, Alexandrescu fails to disclose any system which is "configured to receive the one or more selected or customized after-care tests from the

> clinician subsystem, and wherein the recipient subsystem communicates with the cochlear implant so as to perform the one or more [cochlear-implant] after-care tests selected or customized on the clinician subsystem." ((See, Alexandrescu, col. 3, ln. 59- col. 4, ln. 19.) As noted, the system of Alexandrescu merely provides programs to a hearing aid. (See, Alexandrescu, col. 3, ln. 59- col. 4, ln. 19.) Alexandrescu lacks any disclosure indicating that the system is capable of providing a patient with the ability to perform cochlear implant "after-care tests" as recited, in part, in claim 139.

The Examiner asserts that this argument with respect to Alexandrescu is not considered to be persuasive as the features argued are already taught by the disclosures of Givens and Faltys, as described above.

Applicant then provides similar arguments with respect to claims 156, 165, and 174 which are not considered to be persuasive for the reasons provided above.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Patent No. 6,334,072 to Leysieffer teaches a system for performing a test on a hearing prosthesis implanted in a recipient (column 8, lines 24-26) comprising: a testing computer (column 6, lines 49-52) comprising a processor configured to process software instructions and to output signals in response to said processed software instructions (column 7, lines 38-52); a prosthesis interface configured to transfer said outputted signals from said testing computer to the hearing prosthesis interfaced with said testing computer (column 6, lines 45-64); and a recipient interface configured to receive a control input from the recipient of the hearing and to

cause said processor to perform said test in response to said control input (column 6, line 65 to column 7, line 7).

U.S. Patent No. 6,115,478 to Schneider teaches an apparatus for and method of programming a digital hearing prosthesis comprising a local system and computer and a remote system and computer wherein the remote system controls the local system to initiate synthesizing signals for transmission to the hearing prosthesis (column 9, lines 50-58).

U.S. Patent No. 6,879,693 to Miller et al. teaches a method and system for external assessment of hearing aids that include implanted actuators.

U.S. Patent Application Publication No. 2002/0176584 to Kates teaches an apparatus and methods for hearing aid performance measurement, fitting, and initialization.

U.S. Patent No. 6,366,863 to Bye et al. teaches a portable hearing-related analysis system.

U.S. Patent No. 6,115,478 to Schneider teaches an apparatus and method of programming a digital hearing aid.

U.S. Patent No. 4,847,617 to Silvian teaches a high speed digital telemetry system for implantable devices.

U.S. Patent No. 5,609,616 to Schulman et al. teaches a physician's testing system and method for testing an implantable cochlear stimulator.

U.S. Patent No. 7,181,297 to Pluvinage et al. teaches a system and method for delivering customized audio data.

EP Patent Application Publication No. 0 124 930 to Crosby et al. teaches a cochlear implant system for an auditory prosthesis.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY R. WEST whose telephone number is (571)272-2226. The examiner can normally be reached on Monday through Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eliseo Ramos-Feliciano can be reached on (571)272-7925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey R. West/
Primary Examiner, Art Unit 2857

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